In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

No. 16-1173V

(Not to be published)

* *		
	*	Special Master Corcoran
BARBARA SHEETS,	*	
	*	Filed: April 30, 2019
Petitioner,	*	
	*	
v.	*	Influenza Vaccine; Tetanus Vaccine; Rippling Muscle Disease; Significant Aggravation.
	*	
SECRETARY OF HEALTH AND HUMAN SERVICES,	*	
	*	
Respondent.	*	
	*	
* *		

Leah V. Durant, Law Offices of Leah V. Durant, PLLC, Washington, DC, for Petitioner.

Julia M. Collison, U.S. Dep't of Justice, Washington, DC, for Respondent.

DECISION DENYING ENTITLEMENT[1]

On September 20, 2016, Barbara Sheets filed this action seeking compensation under the National Vaccine Injury Compensation Program (the "Vaccine Program"[2]). Petition ("Pet.") (ECF No. 1). Petitioner alleges that she developed Rippling Muscle Disease ("RMD") after receipt of the influenza ("flu") and tetanus vaccines on December 23, 2013, and/or that an underlying autoimmune condition was significantly aggravated by these vaccines. Pet. at 1.

[1] Although this Decision has not formally been designated for publication, it will ultimately be posted on the United States Court of Federal Claims' website, in accordance with the E-Government Act of 2002, 44 U.S.C. § 3501 (2012). **This means the ruling will be available to anyone with access to the internet**. As provided by 42 U.S.C. § 300aa-12(d)(4)(B), however, the parties may object to the published Decision's inclusion of certain kinds of confidential information. Specifically, under Vaccine Rule 18(b), each party has fourteen (14) days within which to request redaction "of any information furnished by that party: (1) that is a trade secret or commercial or financial in substance and is privileged or confidential; or (2) that includes medical files or similar files, the disclosure of which would constitute a clearly unwarranted invasion of privacy." Vaccine Rule 18(b). Otherwise, the entire Decision will be available in its current form. *Id.*

[2] The Vaccine Program comprises Part 2 of the National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755 (codified as amended at 42 U.S.C. § 300aa-10 through 34 (2012)) (hereinafter "Vaccine Act" or "the Act"). All subsequent references to sections of the Vaccine Act shall be to the pertinent subparagraph of 42 U.S.C. § 300aa.

Following the filing of Petitioner's medical records and expert reports, I informed the parties that I intended to resolve this matter on the record. Petitioner filed a brief in support of her claim on November 9, 2018. ECF No. 30 ("Mot."). Respondent thereafter opposed Petitioner's entitlement to a damages award by brief dated November 30, 2018. ECF No. 31 ("Opp."). Petitioner filed a reply on December 28, 2018. ECF No. 33 ("Reply"). Having completed my review of the evidentiary record and the parties' filings, I hereby DENY Petitioner's request for compensation, for the reasons stated below.

I. Factual Background

Petitioner was born on August 30, 1964. Pet. at 1. By 2010 (three years before the vaccinations at issue), Petitioner was believed to be suffering from an undifferentiated or mixed connective tissue disease—an autoimmune disease characterized by the signs and symptoms of a combination of disorders (typically lupus, scleroderma and polymyositis). Ex. 2 at 4, filed Dec. 16, 2016 (ECF No. 6); *Dorland's Illustrated Medical Dictionary* 539 (32nd ed. 2012) (hereinafter "*Dorland's*"). Although Petitioner's symptoms abated over time, they never entirely resolved. *See* Ex. 5 at 1–4, filed Dec. 16, 2016 (ECF No. 6); Ex. 36 at 6–8, filed Mar. 31, 2017 (ECF No. 11-1) (fatigue and abdominal pain noted at December 4, 2013 visit).

In early December 2013, Petitioner was noted by gynecologist Neil Rosenshein, M.D., to be suffering from a recurrent MRSA infection.[3] Ex. 36 at 9. Later that month, on December 23, 2013, Petitioner received the flu and tetanus-diphtheria-acellular pertussis ("Tdap") vaccines. Ex. 3 at 25, filed Dec. 16, 2016 (ECF No. 6). Thereafter, in early 2014, Ms. Sheets had several encounters with medical providers (whether for a surgical procedure or visits to various specialists), but at no time did she report any symptoms that might be considered consistent with RMD, nor did she recount experiencing any reaction to her late-December vaccinations. *See* Ex. 3 at 14–15 (January 3, 2014, surgery to remove a pelvic mass); Ex. 36 at 4–5 (January 13, 2014, post-surgical visit); Ex. 4 at 1–7, filed Dec. 16, 2016 (ECF No. 6) (denying leg cramps to cardiologist on January 17 and 24, 2014); Ex. 5 at 1–4 (March 5, 2014 visit with rheumatologist Enrico Villanueva, M.D.; Petitioner reporting intermittent pain/swelling of the hands, but no record of other symptoms).

By early spring 2014 (several months after the December 23, 2013 vaccinations), Petitioner began reporting rippling muscle symptoms to one of her medical providers, Bruce Edwards, M.D. Ex. 6 at 1–4, filed Dec. 16, 2016 (ECF No. 6) (April 23, 2014 visit). Ms. Sheets stated at this time that her symptoms had actually begun just after her late December vaccinations, although there is no prior contemporaneous medical record memorializing such a complaint. *Id.* Medical examination revealed Petitioner's strength to be normal (at 5 out of 5). *Id.* at 3. Dr. Edwards noted progressively worsening symptoms, and posited that her condition could be related to either the flu vaccine or her pre-vaccination mixed connective tissue disease. *Id.* at 1, 4.

[3] An MRSA [methicillin-resistant *Staphylococcus aureus*] infection is a staph infection that is resistant to normal antibiotic treatment. *Dorland's* at 1185, 1765.

Over the next few months, Ms. Sheets's symptoms worsened. Beginning in June 2014 (now more than five months post-vaccination), Petitioner repeatedly saw neurologist Mehrullah Khan, M.D., who noted that her muscular twitching affected her arms and calves as well as her thighs, and that she had begun to experience muscle weakness and difficulty swallowing. Ex. 7 at 2, filed Dec. 16, 2016 (ECF No. 6). Dr. Khan initially theorized that Petitioner had a motor neuron disease, but later modified his diagnosis to polymyositis.[4] *Id.* at 3, 4, 18, 20. After a biopsy of her left quadriceps muscle revealed a nonspecific myopathy,[5] Dr. Khan referred Ms. Sheets to a neuromuscular clinic. *See id.* at 8, 22; Ex. 3 at 8–9.

On Dr. Khan's referral, Petitioner saw Zachary Simmons, M.D., a neurologist at the Penn State neuromuscular clinic on September 4, 2014. Ex. 3 at 31–34. At this time, Ms. Sheets reported that her condition was affecting her ability to perform daily living tasks. *Id.* at 31–32. Dr. Simmons proposed a diagnosis of RMD—the first time a treater discussed this diagnosis—and suggested that she also had mixed connective tissue disease. *Id.* at 33. Because Petitioner reported her symptoms had begun shortly after vaccination, Dr. Simmons noted that "[i]t is possible that the vaccination triggered an autoimmune reaction that unmasked/brought an underlying neuromuscular disease to the forefront." *Id.* Dr. Simmons ordered genetic testing to determine whether Petitioner had the hereditary form of RMD, and referred her for follow-up with rheumatology. *Id.* Her genetic testing, however, showed that she was negative for mutations in the caveolin 3 gene, ruling out the hereditary form of the disease. *See* Ex. 22 at 435, filed Dec. 16, 2016 (ECF No. 6).

Petitioner next saw Shirley Albano-Aluquin, M.D., on September 15, 2014, for a rheumatology consultation. Ex. 3 at 36–39. At this initial visit, Dr. Albano-Aluquin assessed Petitioner as likely having a secondary form of myositis attributable to her mixed connective tissue disease. *Id.* at 38. Over subsequent visits, Dr. Albano-Aluquin's assessment evolved to include possible diagnoses of chronic severe mixed pain, systemic lupus, and "autoimmune mediated muscle disease." Ex. 20 at 3–4, filed Dec. 16, 2016 (ECF No. 6) (January 20, 2015 note).[6] Despite various treatments, Petitioner's symptoms continued to worsen, eventually including blurred vision. Ex. 22 at 43.

In May of 2015, Drs. Albano-Aluquin and Simmons referred Petitioner to a muscle disease expert, Matthew Wicklund, M.D. Ex. 22 at 55. Ms. Sheets saw Dr. Wicklund on July 8th, at which time he expressed the firm conclusion that she had RMD. Ex. 3 at 62–65. He theorized that her RMD was autoimmune in nature, and suggested that she might also have lupus and neuromuscular junction disease.

[4] Polymyositis is a chronic, progressive muscle inflammation disease, often featuring symmetrical pain and weakness. *Dorland's* at 1490.

[5] A myopathy is any disease of the muscles. *Dorland's* at 1224.

[6] An undated progress note included with Petitioner's medical record states that Dr. Albano-Aluquin diagnosed Petitioner with RMD on July 20, 2015. Ex. 25 at 10, filed Dec. 16, 2016 (ECF No. 6). It is unclear whether a primary record exists from that July 20th visit, however.

Id. at 65. Ms. Sheets soon thereafter began intravenous immunoglobulin ("IVIG") treatment, which led to significant improvement. *Id.* at 66 (September 3, 2015 note); Ex. 22 at 1 (November 18, 2015 note describing improvement lasting for two to three weeks at a time).

By March 2016, Dr. Wicklund assessed Ms. Sheets's RMD as significantly improved, largely due to the IVIG treatment. Ex. 25 at 12. Petitioner characterized herself as able to function at fifty percent of her prior capacity, and her muscles had almost entirely stopped rippling. *Id.* at 11. However, the most recent medical records filed, from January 2017, reveal that Petitioner still suffers from mild to moderate pain related to her connective tissue disease. Ex. 33 at 26, filed Mar. 6, 2017 (ECF No. 10-2).

II. Expert Reports

A. *Petitioner's Expert: Dr. John Rinker*

Dr. Rinker authored three expert reports in support of Petitioner's claim. *See* Ex. 37, filed Oct. 30, 2017 (ECF No. 17-1) ("First Rinker Rep."); Ex. 54, filed Nov. 28, 2017 (ECF No. 18-1) ("Second Rinker Rep."); Ex. 62, filed June 17, 2018 (ECF No. 26-1) ("Third Rinker Rep"). He opined that Ms. Sheets either developed RMD as a result of the flu and/or tetanus vaccines, or that her RMD reflected a vaccine-induced significant aggravation of an underlying autoimmune condition. First Rinker Rep. at 8.

As set forth in his curriculum vitae ("CV"), Dr. Rinker is an associate professor of neurology at the University of Alabama at Birmingham. Ex. 38 at 1, filed Oct. 30, 2017 (ECF No. 17-2). He spends part of his time as an attending neurologist at the University of Alabama at Birmingham hospital, where he specializes in treatment of patients with multiple sclerosis and related disorders. *Id.* at 1, 4. He received his B.A. from Wake Forest University and his M.D. from the Medical College of Georgia. *Id.* at 2. He completed an internship and neurology residency at the Washington University School of Medicine in St. Louis, Missouri. *Id.* He has published fifteen peer-reviewed articles and four book chapters, most of which focus on multiple sclerosis. *Id.* at 4, 11–12. He does not, however, appear to have any notable expertise in immunologic matters (other than what he might indirectly have obtained from his neurology practice).

In his first report, Dr. Rinker admitted that because Ms. Sheets had previously been diagnosed with an autoimmune disorder, distinguishing between causation-in-fact and significant aggravation in this case would be difficult. First Rinker Rep. at 1. Based on Petitioner's medical records and her own descriptions of her history, however, Dr. Rinker concluded that her condition was accurately characterized as autoimmune RMD and could be attributed to the flu and/or tetanus vaccines she received in December 2013. *Id.* at 4, 8.

In discussing the correct diagnosis, Dr. Rinker acknowledged in his first report that "no formal diagnostic criteria for RMD exist." First Rinker Rep. at 4. He nevertheless concluded that Ms. Sheets likely had autoimmune RMD based on "her symptoms and the signs observed by her treating physicians," her lack of a genetic variant that would indicate genetic RMD, the diagnosis made in September 2014 by Dr. Simmons, and her positive response to immune modulatory treatment. *Id.*

Dr. Rinker next considered several possible theories of vaccine causation that might apply to Ms. Sheets's case. First Rinker Rep. at 6–7. In particular, he discussed the theory of molecular mimicry, a biologic mechanism for many other known autoimmune diseases (such as Guillain-Barré syndrome ("GBS")). *Id.* at 6. Under this theory as described by Dr. Rinker, a person's immune response to an infectious agent (or vaccine) is aberrant, resulting in a failure to discern between foreign antigens and self, causing an inadvertent immune reaction against "self-antigens which can result in immune-mediated harm to otherwise healthy tissues." *Id.* Dr. Rinker did not offer any literature specifically relating vaccination or wild virus infection to onset of RMD via this process, however.

Dr. Rinker also proposed that Ms. Sheets's pre-existing conditions impacted the molecular mimicry process his theory relied upon. His first report discussed human leukocyte antigens ("HLA"), polymorphic molecules that present foreign antigens (that would be contained in vaccines) to the immune system. First Rinker Rep. at 6. He explained that an individual's unique HLA complex "is thought to play a role in many idiosyncratic drug and vaccine reactions." *Id.* (citing J. Uetrechy & D. Naisbitt, *Idiosyncratic Adverse Drug Reactions: Current Concepts*, 65 Pharmacological Rev. 779 (2013), filed as Ex. 50, Oct. 30, 2017 (ECF No. 17-14)). At bottom, he noted that "the critical factor" in determining a patient's susceptibility to autoimmune conditions such as RMD was the person's "unique immunological background (including HLA type) and how it interacts with vaccines." *Id.* at 7. Given Ms. Sheets's history of autoimmune disease, Dr. Rinker theorized that she was likely predisposed to autoimmunity, and therefore the vaccines she received on December 23, 2013, would likely have triggered her subsequent symptoms that ultimately led to an RMD diagnosis. *Id.*

Finally, Dr. Rinker discussed the possible role of adjuvants included in the vaccines Petitioner received in instigating an autoimmune reaction. Adjuvants are expressly included in vaccines to boost the adaptive immune response (so that the body manufactures antibodies that will in the future recognize the virus or bacterium that the vaccine is intended to address), but that literature supported the possibility that adjuvants could also increase the production of antibodies "directed at antigens commonly associated with systemic autoimmunity in humans." First Rinker Rep. at 6 (citing J. Murphy-Ullrich, et al., *Detection of Autoantibodies and Glomerular Injury in Rabbits Immunized with Denatured Human Fibronectin Monomer*, 117 Anti-Fibronectin Autoantibodies 1 (1984), filed as Ex. 44, Oct. 30, 2017 (ECF No. 17-8) ("Murphy-Ullrich")). He admitted, however, that Murphy-Ullrich did not observe a pathogenic result from the increased production of such autoantibodies. *Id.* And Dr. Rinker's first report did not otherwise establish, with reliable scientific literature, that any adjuvant in the Tdap vaccine (since the flu vaccine administered in the U.S. does *not* contain an adjuvant)[7] has been shown to be associated with RMD or a

[7] The records filed in this case do not specify precisely which seasonal flu vaccine Petitioner received. However, as noted by the Centers for Disease Control and Prevention (the "CDC"), virtually *all* flu vaccines administered in the United States contain no adjuvant. Centers for Disease Control and Prevention, Adjuvants Help Vaccines Work Better, CDC (Oct. 22, 2018), https://www.cdc.gov/vaccinesafety/concerns/adjuvants html. Petitioner's vaccination consent form indicates that she received a vaccine manufactured by Sanofi Pasteur (Ex. 1 at 1–2, filed Dec. 16, 2016 (ECF No. 6)), while the single adjuvanted flu vaccine in the United States (FLUAD) is manufactured by Seqirus. Centers for Disease Control and Prevention, Flu Vaccine With Adjuvant, CDC (Oct. 18, 2018), https://www.cdc.gov/flu/protect/vaccine/adjuvant htm. It is thus reasonable to infer that whatever flu vaccine Petitioner received was unadjuvanted.

similar condition. Indeed, he conceded that his literature search had revealed *no* case reports reflecting post-vaccination RMD. *Id.*

Dr. Rinker's first report also briefly addressed the timing of Petitioner's onset. Based on statements Ms. Sheets made to him, Dr. Rinker opined that her RMD began approximately one day after vaccination. First Rinker Rep. at 7. Stating that he would expect a peak immune response within a few days of vaccination, Dr. Rinker deemed her subsequent course logically consistent with vaccine causation. *Id.* He noted as well, however, that the existing medical records themselves were inconsistent with her reported onset, since they do not record any complaints of muscle problems or weakness immediately after vaccination. *Id.* at 3.

Dr. Rinker filed his first supplemental report at my request, addressing two specific issues. *See* Scheduling Order, dated Nov. 14, 2017 (non-PDF docket entry). First, he discussed in greater detail the medical record evidence supporting Ms. Sheets's statement that her RMD symptoms began in the days immediately following vaccination. Second Rinker Rep. at 1. He pointed to her March 5, 2014 visit with rheumatologist Dr. Villanueva (which occurred over two months after vaccination) as the earliest possible evidence of Petitioner's symptoms, as Ms. Sheets checked boxes indicating muscle aches, muscle weakness, and joint pain at that visit. *Id.* (discussing Ex. 5). Dr. Rinker then turned to the related question of the likelihood of vaccine causation if Ms. Sheets's condition in fact began not in December, but at the time reflected in the medical records (spring 2014). *Id.* at 2. He conceded that "establishing the time of symptom onset as late as late March or early April 2014 would lessen the likelihood that Ms. Sheets' rippling muscle disease could be ascribed to her vaccinations on 12/23/2013," explaining that case reports for analogous vaccine-caused autoimmune reactions typically showed onset within one to two weeks of vaccination. *Id.* While he maintained his belief that Petitioner's symptoms began in December 2013 (as she had informed him), Dr. Rinker stated that additional accounts describing her earliest symptoms would "help to more confidently establish the time of onset." *Id.*

In his second supplemental report, Dr. Rinker discussed the possibility that one or both of the December 23, 2013 vaccines Ms. Sheets received had significantly aggravated her underlying autoimmune condition. He noted that Petitioner had suffered from systemic autoimmunity more than three years before vaccination, but had responded well to immune modulating therapy, and was "in remission" at the time of vaccination. Third Rinker Rep. at 1. After vaccination, by contrast, her condition declined sharply, which Dr. Rinker characterized as "a continuation of her previously diagnosed autoimmune condition." *Id.* at 2. A vaccine, he theorized, could significantly aggravate a latent, pre-existing condition by provoking a systemic immune response shortly after vaccination. *Id.* He did not, however, offer literature supporting this contention, relying instead on the absence of evidence of *other* explanations as leaving the vaccine as most likely causal. *Id.*

B. *Respondent's Expert: Dr. Vinay Chaudhry*

Respondent's expert, Vinay Chaudhry, M.D., submitted a single expert report in this case. *See* Ex. A, filed Apr. 12, 2018 (ECF No. 24-1) ("Chaudhry Rep."). Dr. Chaudhry opined that Ms. Sheets's April

2014 myopathy symptoms are attributable to her pre-vaccination connective tissue disease rather than the vaccines she received, and that she does *not* in fact have RMD. *Id.* at 9–10, 15.

As shown in his CV, Dr. Chaudhry works as a professor of neurology at Johns Hopkins University School of Medicine. Ex. B at 1, filed Apr. 12, 2018 (ECF No. 24-2). He also works as an attending physician at Johns Hopkins hospital for part of the year, and he serves as co-director of the Neurology EMG [electromyography] Laboratory there. *Id.* at 1, 29–30. Dr. Chaudhry received his B.S. and M.D. at All India Institute of Medical Sciences in New Delhi, India, and many years later received his M.B.A. at Johns Hopkins. *Id.* at 2. He completed his residency in neurology at the University of Alabama at Birmingham, followed by a fellowship in neuromuscular diseases at Johns Hopkins. *Id.* at 2–3. He has published dozens of peer-reviewed articles and book chapters, largely focusing on neuromuscular disease. *Id.* at 3–12.

Based on his medical expertise and review of Petitioner's records, Dr. Chaudhry opined that Petitioner did not in fact have RMD, but rather had experienced a resurgence of her pre-existing connective tissue disease. Chaudhry Rep. at 11, 15. As he explained, there are two types of RMD: inherited (corresponding to a caveolin 3 genetic variant) and immune-mediated. *Id.* at 10–11. Ms. Sheets unquestionably did not have inherited RMD, as she lacks the requisite genetic variant. *Id.* But *all* acquired cases of immune-mediated RMD noted in the literature cited by Dr. Rinker, Dr. Chaudhry observed, were associated with myasthenia gravis[8] or with abnormal electrophysiology. *Id.* at 11. Ms. Sheets, however, presented with neither. *Id.* Additionally, Ms. Sheets experienced numerous symptoms not associated with RMD, including severe weakness, a progressive course, myotonic discharges visible in an EMG, joint pain, stiffness, swelling, fatigue, rash, and a lack of muscle hypertrophy. *Id.* at 10–11. Finally, Dr. Chaudhry noted that the fact that Ms. Sheets responded to immune modulating therapy should not be considered evidence of RMD, as the same treatment could be used for a range of immune and mixed connective tissue diseases. *Id.* at 10.

Dr. Chaudhry also disputed that the vaccines Petitioner received in late December 2013 could have caused new symptoms and/or aggravated her existing connective tissue disease condition. He expressed awareness of published literature suggesting that certain infections (such as MRSA, which Petitioner was diagnosed with approximately three weeks before she received the Tdap vaccine) could exacerbate connective tissue disease symptoms, but disputed that equally reliable literature existed establishing that a vaccination could have the same effect. Chaudhry Rep. at 11 (citing T. Acvin, et al., *Infections, Connective Tissue Diseases and Vasculitis*, 26 Clinical & Experimental Rheumatology S-18 (2008), filed as Ex. F, Apr. 12, 2018 (ECF No. 24-6); Inst. of Med., *Adverse Effects of Vaccines: Evidence and Causality* 335–89, 567–81 (2012), filed as Ex. C, Apr. 12, 2018 (ECF No. 24-3)).

Dr. Chaudhry went on to review the literature relied upon by Dr. Rinker in support of a molecular mimicry theory of causation, explaining why in his opinion each article failed to support Dr. Rinker's theory. Chaudhry Rep. at 12–14. In particular, he noted that Dr. Rinker cited to literature discussing

[8] Myasthenia gravis is an autoimmune condition affecting neuromuscular function. *Dorland's* at 1214.

illnesses that Petitioner unquestionably did not have, including idiopathic thrombocytopenic purpura, acute disseminated encephalomyelitis, GBS, autoimmune hepatitis, and idiosyncratic drug reactions. *Id.* at 12–13. He noted further that the literature Dr. Rinker relied on when discussing adjuvants in fact concluded that adjuvants had *no* pathogenic effect. *Id.* at 13. Other items of literature cited by Dr. Rinker found no vaccine-related aggravation of conditions such as multiple sclerosis and rheumatic diseases. *Id.* In sum, Dr. Chaudhry opined that Petitioner's "immune muscle disease wasn't caused or made worse by the vaccination." *Id.* at 16.

III. Other Fact Evidence

Ms. Sheets has not filed an affidavit of her own,[9] but offered multiple witness and treater statements in this case. First, Petitioner filed affidavits from family and friends. The first three—one each from her husband, daughter and brother-in-law, all dated in 2017—discuss the onset of her symptoms. *See* Ex. 55, filed Dec. 7, 2017 (ECF No. 19-1) (affidavit of husband, Raymond Sheets); Ex. 56, filed Dec. 7, 2017 (ECF No. 19-2) (affidavit of daughter, Lauren Sheets); Ex. 61, filed Dec. 8, 2017 (ECF No. 20-1) (affidavit of brother-in-law, Ryan Clark). All purport to recall rippling muscle/myopathy symptom onset immediately following Petitioner's December 2013 vaccinations.

Ms. Sheets's husband stated that she began to notice tingling in her legs on Christmas Eve of 2013. Ex. 55 at 1. Her daughter reiterated that Ms. Sheets experienced leg tingling on Christmas Eve, and added that a few weeks later, while planning a birthday party for Ms. Sheets's granddaughter in mid-January, Ms. Sheets experienced extreme pain when her three-year-old granddaughter jumped into her lap. Ex. 56 at 1. Ms. Sheets's brother-in-law stated that he learned about her illness "a short time before Christmas of 2013." Ex. 61 at 1. The remaining four witness statements discuss the extent of her damages, rather than onset. *See* Ex. 57, filed Dec. 7, 2017 (ECF No. 19-3) (affidavit of former coworker, Whitney Eckert); Ex. 58, filed Dec. 7, 2017 (ECF No. 19-4) (affidavit of son Brandon Allen); Ex. 59, filed Dec. 7, 2017 (ECF No. 19-5) (affidavit of family friend, Carrie Earl); Ex. 60, filed Dec. 7, 2017 (ECF No. 19-6) (affidavit of mother, Diane Gorby).[10]

Second, Petitioner has offered treater statements on causation theory points. Two of her treaters—a rheumatologist, Dr. Albano-Aluquin, who Petitioner first saw in September 2014 (nine months post-vaccination), and a neuro-muscular physician, Dr. Wicklund, whom Petitioner first saw in July 2015 (seventeen months post-vaccination)—offered letters dated May and August 2016, respectively. *See*

[9] Petitions for compensation brought under the Vaccine Act must be accompanied by an affidavit demonstrating that the petitioner meets basic statutory requirements (such as having received a vaccine covered by the Act, not having previously collected an award or settlement for the claimed vaccine-related injury, etc.). Section 11(c)(1).

[10] Petitioner's primary expert, Dr. Rinker, also has represented that she informed him during an October 3, 2017 phone call that her symptoms began soon after her 2013 vaccination. *See* First Rinker Rep. at 5. Of course, such non-contemporaneous statements (putting aside their obvious hearsay quality) have minimal probative value, especially given that they were made after this action had been initiated.

Ex. 31 at 129, 241–42, filed Dec. 16, 2016 (ECF No. 6). Dr. Wicklund stated that "[a]lthough there is no way to know for sure that vaccinations caused Ms. Sheets disease; vaccines are known to increase the likelihood of autoimmune disorders, and Ms. Sheets rippling muscle disease is immunoresponsive." *Id.* at 129 (May 14, 2016 letter). Dr. Albano-Aluquin's initial position was more tentative, proposing that "[w]hile her condition is immune mediated and occurred after vaccination, the mechanisms including causes and triggers of the disease remain unclear." Ex. 31 at 241–42 (May 23, 2016 letter). However, a subsequent letter from Dr. Albano-Aluquin, dated August 3, 2016, stated that "[w]hile there is no direct association or evidence that can prove causation, I believe that her mixed autoimmune disease may have flared as a result of stress, illness, and the flu vaccination." Ex. 29 at 1, filed Dec. 16, 2016 (ECF No. 6).[11]

IV. Procedural Background

On September 20, 2016, Ms. Sheets initiated her claim. Respondent filed his Rule 4(c) Report on May 26, 2017, disputing Petitioner's entitlement to damages. Respondent's Rule 4(c) Report at 13–14 (ECF No. 15). A year later, Petitioner filed Dr. Rinker's expert report and supporting literature. After a status conference on November 14, 2017, Dr. Rinker filed a supplemental report clarifying his opinion regarding the onset of Petitioner's injury. On April 12, 2018, Respondent filed a responsive expert opinion and medical literature from Dr. Chaudhry, prompting Petitioner to file a third report from Dr. Rinker on June 17, 2018. I thereafter determined that the matter was best resolved on the record, and ordered the parties to file briefs in support of their respective positions (although I also indicated that I would entertain arguments from either side as to the propriety of a trial). The matter is now ripe for resolution.

V. Parties' Respective Arguments

A. *Petitioner*

Petitioner argues that she does in fact have RMD. Mot. at 10–14. In support, she points to the diagnoses of three treaters: Dr. Simmons, who stated in September 2014 that her symptoms were suggestive of RMD; Dr. Wicklund, who diagnosed her with RMD on July 8, 2015; and Dr. Albano-Aluquin, who diagnosed Petitioner with RMD on July 20, 2015. *Id.* at 11–12 (citing Ex. 8 at 3, filed Dec. 16, 2016 (ECF No. 6); Ex. 3 at 65; Ex. 25 at 10). Because Dr. Chaudhry does not accept this RMD diagnosis in the face of the medical record, she contends, his entire opinion should be given little to no weight. Reply at 2.

Petitioner next maintains that she has made a satisfactory showing of causation-in-fact under the Federal Circuit causation test set forth in *Althen v. Secretary of Health & Human Services*, 418 F.3d 1274 (Fed. Cir. 2005), or in the alternative, that she has satisfied the significant aggravation test set forth in

[11] It appears that Petitioner's counsel not only solicited these letters, but (in the case of Dr. Albano-Aluquin) provided a draft letter. *See* Ex. 31 at 37–41, 241–42, 273–74.

Loving v. Secretary of Health & Human Services, 86 Fed. Cl. 135, 144 (2009). As a legal matter, she contends that she need only show that her proffered theory of causation is *plausible*. Mot. at 15 (citing *Tarsell v. Sec'y of Health & Human Servs.*, 133 Fed. Cl. 782, 792–93 (2017); *Contreras v. Sec'y of Health & Human Servs.*, 121 Fed. Cl. 230, 245 (2015), *vacated on other grounds*, 844 F.3d 1363 (Fed. Cir. 2017)). She asserts that the theories put forth by Dr. Rinker satisfy this plausibility standard, and emphasizes that molecular mimicry in particular has been repeatedly accepted in the Vaccine Program as a causation mechanism. *Id.* at 15–16 (citing *Quackenbush-Baker v. Sec'y of Health & Human Servs.*, No. 14-1000V, 2018 WL 1704523, at *16–17 (Fed. Cl. Spec. Mstr. Mar. 14, 2018)). Additionally, Petitioner argues that her condition should *not* be viewed as a continuation of prior autoimmune disorder, as she had never previously experienced specific symptoms relevant to the diagnosis, like rippling muscles. Reply at 5.

Petitioner further argues that she has shown that the vaccines at issue caused her RMD. In support, she relies on the opinions of treating doctors. Mot. at 18–19. Specifically, she notes that Dr. Simmons believed it "possible that the vaccination triggered an autoimmune reaction that unmasked/brought an underlying neuromuscular disease to the forefront." *Id.* at 18 (citing Ex. 8 at 3). She also highlights the letter provided by Dr. Wicklund. *Id.* at 18–19 (citing Ex. 28 at 1, filed Dec. 16, 2016 (ECF No. 6)). Finally, Petitioner points to Dr. Albano-Aluquin's letter, which states: "While there is no direct association or evidence that can prove causation, I believe that her mixed autoimmune disease may have flared as a result of stress, illness, and the flu vaccination." *Id.* at 19 (citing Ex. 29 at 1). Additionally, Petitioner notes that none of her treating doctors ever considered her December 2013 MRSA infection to be a likely trigger for her condition. Reply at 6.

Turning to the third *Althen* prong, Petitioner asserts that the flu and tetanus vaccines caused her illness within a medically-acceptable timeframe. Mot. at 20–22. Relying on her own recollections of symptom onset and the statements provided by her friends and family, Petitioner asserts that onset within a few days after vaccination is a reasonable timeframe under Dr. Rinker's causation theories. *Id.* at 20–21. She contends that, although there is no medical record evidence corroborating her allegations of symptoms beginning in the weeks following vaccination, her stated version of events is not specifically *contradicted* by existing medical records either. *Id.* at 21.

Finally (and somewhat contrary to her prior position that the vaccines did not aggravate her pre-existing connective tissue disease), Petitioner asserts that she has also satisfied the *Loving* criteria and has shown that the flu and tetanus vaccines significantly aggravated an underlying condition—specifically, a "predisposition to autoimmunity." Mot. at 22–25. She describes her pre-vaccination condition and how she became markedly worse after vaccination. *Id.* at 23–24. She notes that treating physicians and Dr. Rinker theorized that vaccines might have been a trigger for her progressive worsening in early 2014. *Id.* at 24–25 (citing Third Rinker Rep. at 1; Ex. 29 at 1). Thus, Ms. Sheets argues that the vaccines significantly aggravated her pre-existing predisposition to autoimmune conditions. *Id.* at 25.

Besides making arguments as to the sufficiency of her evidentiary showing, Petitioner argues that a hearing is necessary to resolve this matter. Mot. at 2; Reply at 4–5. In particular, she notes that a hearing would allow for direct and cross examination of experts, and would permit her to call treating physicians and other fact witnesses to testify about when her symptoms began. Mot. at 2; Reply at 4–5.

B. *Respondent*

In arguing against compensation, Respondent contends that Petitioner did not have RMD, and also that her illness was not caused or significantly aggravated by vaccines. With regard to her diagnosis, Respondent asserts that, as stated by Dr. Chaudhry, Ms. Sheets in fact suffers from a myopathy following connective tissue disease. Opp. at 10–11 (citing Chaudhry Rep. at 10–11). Throughout her visits with various treaters, Petitioner's condition was frequently characterized as some form of myopathy. *Id.* at 10 (citing Ex. 6 at 1–4; Ex. 7 at 8; Ex. 3 at 38, 62–65; Ex. 23 at 38–44, filed Dec. 16, 2016 (ECF No. 6)). Respondent also points out that neither Petitioner's treaters nor Dr. Rinker ever denied the possibility that her illness was a continuation of her prior autoimmune condition, and that several doctors, including Petitioner's own expert, expressly stated that it was likely so. *Id.* at 11 (citing Third Rinker Rep. at 2 (Dr. Rinker stating that Petitioner's illness "is best viewed as a continuation of her previously diagnosed autoimmune condition, rather than a completely *de novo* condition"); Ex. 29 at 1 (Dr. Albano-Aluquin describing Petitioner's symptoms as a "flare")).

Respondent also asserts that Petitioner has failed to satisfy all three *Althen* prongs (and thus has also failed to satisfy the *Loving* standard for significant aggravation). As a threshold matter, Respondent argues that Petitioner mischaracterizes the standard for the showing she must make under *Althen* prong one. Opp. at 15–16. Rather, he argues that mere plausibility or possibility is insufficient, as the Federal Circuit has repeatedly ruled. *Id.* at 15 (citing *LaLonde v. Sec'y of Health & Human Servs.*, 746 F.3d 1334, 1339 (Fed. Cir. 2014); *W.C. v. Sec'y of Health & Human Servs.*, 704 F.3d 1352, 1356 (Fed. Cir. 2013)).

Respondent next maintains that Petitioner's proffered theory of causation is too general and vague to satisfy *Althen* prong one. Opp. at 15–16. None of the components of Petitioner's theory are specific to either the vaccines at issue or her claimed illness, nor does Dr. Rinker cite any literature establishing otherwise. *Id.* at 16. The opinions of Petitioner's treating physicians are similarly nonspecific. *Id.* (discussing Ex. 28 at 1; Ex. 29 at 1). While Petitioner points to *Quackenbush-Baker* to demonstrate that molecular mimicry has been accepted as a theory of causation in the Vaccine Program, Respondent points out that "in that case petitioner's expert set forth a homology sequence that was deemed to be reliable by the special master; no homology was postulated here." *Id.* at 16 n.7. Asserting that "molecular mimicry is not a catch-all explanation for how any vaccination can cause any immune-related injury," Respondent argues that Petitioner's showing on *Althen* prong one is insufficient. *Id.* at 16.

Respondent argues further that Petitioner has not demonstrated that the vaccines at issue were the cause-in-fact or source of significant aggravation of her illness. Opp. at 17–18. Relying on Dr. Chaudhry's

expert report, Respondent states that it is more likely that Petitioner's symptoms were a manifestation of her pre-existing autoimmune disease, particularly as Petitioner had demonstrated some ongoing symptoms of her autoimmune disease before vaccination. *Id.* at 17 (citing Ex. 36 at 6–11; Ex. 5 at 15). The view that Petitioner's RMD is a continuation of her pre-existing condition is supported by both Dr. Rinker and Dr. Albano-Aluquin. *Id.* (citing Ex. 29 at 1; Third Rinker Rep. at 2). And to the extent that there may have been a trigger for this flare-up of Ms. Sheets's pre-existing condition, Respondent argues that it was more likely her December 2013 MRSA infection. *Id.* Respondent notes that Dr. Chaudhry identified medical literature linking bacterial infections to onset of other autoimmune conditions such as polymyositis and dermatomyositis. *Id.* at 17–18 (citing Chaudhry Rep. at 11). Because Dr. Rinker did not address the possibility of the MRSA infection triggering Petitioner's flare, Respondent asserts that Petitioner failed to demonstrate that the vaccines were more likely than not the cause-in-fact of her illness. *Id.* at 18.

Finally, Respondent asserts that Petitioner's illness did not develop within a medically reasonable timeframe after vaccination. Opp. at 11–15. Relying on the lack of reference in Petitioner's medical records to RMD-like symptoms until several months after vaccinations, Respondent contends that Petitioner's post-vaccination symptoms likely did not begin until April 2014. *Id.* at 11–12. Later-in-time records dating the start of Petitioner's symptoms to December 2013, as well as affidavits stating the same, are at odds with records from early 2014 showing no such symptoms, as well as records indicating that she experienced her most severe symptoms in summer and fall of 2014. *Id.* at 12–14. Because Petitioner's own expert conceded that onset more than eight weeks after vaccination would be unreasonable under his proffered theory, Respondent contends that Petitioner's condition did not develop within a medically-appropriate timeframe to satisfy *Althen* prong three. *Id.* at 14–15.

VI. Applicable Law

A. *Petitioner's Overall Burden in Vaccine Program Cases*

To receive compensation in the Vaccine Program, a petitioner must prove either: (1) that he suffered a "Table Injury"—i.e., an injury falling within the Vaccine Injury Table—corresponding to one of the vaccinations in question within a statutorily prescribed period of time or, in the alternative, (2) that his illnesses were actually caused by a vaccine (a "Non-Table Injury"). *See* Sections 13(a)(1)(A), 11(c)(1), and 14(a), as amended by 42 C.F.R. § 100.3; § 11(c)(1)(C)(ii)(I); *see also Moberly v. Sec'y of Health & Human Servs.*, 592 F.3d 1315, 1321 (Fed. Cir. 2010); *Capizzano v. Sec'y of Health & Human Servs.*, 440 F.3d 1317, 1320 (Fed. Cir. 2006).[12] In this case, Petitioner does not assert a Table claim.

[12] Decisions of special masters (some of which I reference in this ruling) constitute persuasive but not binding authority. *Hanlon v. Sec'y of Health & Human Servs.*, 40 Fed. Cl. 625, 630 (1998). By contrast, Federal Circuit rulings concerning legal issues are binding on special masters. *Guillory v. Sec'y of Health & Human Servs.*, 59 Fed. Cl. 121, 124 (2003), *aff'd* 104 F. App'x 712 (Fed. Cir. 2004); *see also Spooner v. Sec'y of Health & Human Servs.*, No. 13-159V, 2014 WL 504728, at *7 n.12 (Fed. Cl. Spec. Mstr. Jan. 16, 2014).

For both Table and Non-Table claims, Vaccine Program petitioners bear a "preponderance of the evidence" burden of proof. Section 13(1)(a). That is, a petitioner must offer evidence that leads the "trier of fact to believe that the existence of a fact is more probable than its nonexistence before [he] may find in favor of the party who has the burden to persuade the judge of the fact's existence." *Moberly*, 592 F.3d at 1322 n.2; *see also Snowbank Enter. v. United States*, 6 Cl. Ct. 476, 486 (1984) (mere conjecture or speculation is insufficient under a preponderance standard). Proof of medical certainty is not required. *Bunting v. Sec'y of Health & Human Servs.*, 931 F.2d 867, 873 (Fed. Cir. 1991). In particular, a petitioner must demonstrate that the vaccine was "not only [the] but-for cause of the injury but also a substantial factor in bringing about the injury." *Moberly*, 592 F.3d at 1321 (quoting *Shyface v. Sec'y of Health & Human Servs.*, 165 F.3d 1344, 1352–53 (Fed. Cir. 1999)); *Pafford v. Sec'y of Health & Human Servs*., 451 F.3d 1352, 1355 (Fed. Cir. 2006). A petitioner may not receive a Vaccine Program award based solely on his assertions; rather, the petition must be supported by either medical records or by the opinion of a competent physician. Section 13(a)(1).

In attempting to establish entitlement to a Vaccine Program award of compensation for a Non-Table claim, a petitioner must satisfy all three of the elements established by the Federal Circuit in *Althen*: "(1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of proximate temporal relationship between vaccination and injury." *Althen*, 418 F.3d at 1278.

Each of the *Althen* prongs requires a different showing. Under *Althen* prong one, petitioners must provide a "reputable medical theory," demonstrating that the vaccine received *can cause* the type of injury alleged. *Pafford*, 451 F.3d at 1355–56 (citations omitted). To satisfy this prong, a petitioner's theory must be based on a "sound and reliable medical or scientific explanation." *Knudsen v. Sec'y of Health & Human Servs.*, 35 F.3d 543, 548 (Fed. Cir. 1994). Such a theory must only be "legally probable, not medically or scientifically certain." *Id.* at 549.

Petitioners may satisfy the first *Althen* prong without resort to medical literature, epidemiological studies, demonstration of a specific mechanism, or a generally accepted medical theory. *Andreu v. Sec'y of Health & Human Servs.*, 569 F.3d 1367, 1378–79 (Fed. Cir. 2009) (citing *Capizzano*, 440 F.3d at 1325–26). Special masters, despite their expertise, are not empowered by statute to conclusively resolve what are essentially thorny scientific and medical questions, and thus scientific evidence offered to establish *Althen* prong one is viewed "not through the lens of the laboratorian, but instead from the vantage point of the Vaccine Act's preponderant evidence standard." *Id.* at 1380. Accordingly, special masters must take care not to increase the burden placed on petitioners in offering a scientific theory linking vaccine to injury. *Contreras*, 121 Fed. Cl. at 245 ("[p]lausibility . . . in many cases *may* be enough to satisfy *Althen* prong one" (emphasis in original)). But this does not negate or reduce a petitioner's ultimate burden to establish his overall entitlement to damages by preponderant evidence. *W.C.*, 704 F.3d at 1356.[13]

[13] Although decisions like *Contreras* suggest that the burden of proof required to satisfy the first *Althen* prong is less stringent than the other two, there is ample contrary authority for the more straightforward proposition that when considering the first

The second *Althen* prong requires proof of a logical sequence of cause and effect, usually supported by facts derived from a petitioner's medical records. *Althen*, 418 F.3d at 1278; *Andreu*, 569 F.3d at 1375–77; *Capizzano*, 440 F.3d at 1326; *Grant v. Sec'y of Health & Human Servs.*, 956 F.2d 1144, 1148 (Fed. Cir. 1992). In establishing that a vaccine "did cause" injury, the opinions and views of the injured party's treating physicians are entitled to some weight. *Andreu*, 569 F.3d at 1367; *Capizzano*, 440 F.3d at 1326 ("medical records and medical opinion testimony are favored in vaccine cases, as treating physicians are likely to be in the best position to determine whether a 'logical sequence of cause and effect show[s] that the vaccination was the reason for the injury'") (quoting *Althen*, 418 F.3d at 1280). Medical records are generally viewed as particularly trustworthy evidence, since they are created contemporaneously with the treatment of the patient. *Cucuras v. Sec'y of Health & Human Servs.*, 993 F.2d 1525, 1528 (Fed. Cir. 1993).

However, medical records and statements of a treating physician do not *per se* bind the special master to adopt the conclusions of such an individual, even if they must be considered and carefully evaluated. Section 13(b)(1) (providing that "[a]ny such diagnosis, conclusion, judgment, test result, report, or summary shall not be binding on the special master or court"); *Snyder v. Sec'y of Health & Human Servs*., 88 Fed. Cl. 706, 746 n.67 (2009) ("there is nothing . . . that mandates that the testimony of a treating physician is sacrosanct—that it must be accepted in its entirety and cannot be rebutted"). As with expert testimony offered to establish a theory of causation, the opinions or diagnoses of treating physicians are only as trustworthy as the reasonableness of their suppositions or bases. The views of treating physicians should be weighed against other, contrary evidence also present in the record—including conflicting opinions among such individuals. *Hibbard v. Sec'y of Health & Human Servs.*, 100 Fed. Cl. 742, 749 (2011) (not arbitrary or capricious for special master to weigh competing treating physicians' conclusions against each other), *aff'd*, 698 F.3d 1355 (Fed. Cir. 2012); *Caves v. Sec'y of Dept. of Health & Human Servs.*, No. 06-522V, 2011 WL 1935813, at *17 (Fed. Cl. Spec. Mstr. Apr. 29, 2011), *mot. for review denied*, 100 Fed. Cl. 344, 356 (2011), *aff'd without opinion*, 475 F. App'x 765 (Fed. Cir. 2012).

The third *Althen* prong requires establishing a "proximate temporal relationship" between the vaccination and the injury alleged. *Althen*, 418 F.3d at 1281. That term has been equated to the phrase "medically-acceptable temporal relationship." *Id.* A petitioner must offer "preponderant proof that the onset of symptoms occurred within a timeframe which, given the medical understanding of the disorder's etiology, it is medically acceptable to infer causation." *de Bazan v. Sec'y of Health & Human Servs.*, 539 F.3d 1347, 1352 (Fed. Cir. 2008). The explanation for what is a medically acceptable timeframe must align with the theory of how the relevant vaccine can cause an injury (*Althen* prong one's requirement). *Id.* at 1352; *Shapiro v. Sec'y of Health & Human Servs.*, 101 Fed. Cl. 532, 542 (2011), *recons. denied after remand*, 105 Fed. Cl. 353 (2012), *aff'd mem.*, 503 F. App'x 952 (Fed. Cir. 2013); *Koehn v. Sec'y of*

prong, the same preponderance standard used overall is also applied when evaluating if a reliable and plausible causal theory has been established. *Broekelschen v. Sec'y of Health & Human Servs*., 618 F.3d 1339, 1350 (Fed. Cir. 2010).

Health & Human Servs., No. 11-355V, 2013 WL 3214877 (Fed. Cl. Spec. Mstr. May 30, 2013), *mot. for review denied* (Fed. Cl. Dec. 3, 2013), *aff'd*, 773 F.3d 1239 (Fed. Cir. 2014).

B. *Legal Framework for Analyzing Significant Aggravation Claims*

In this matter, Petitioner maintains that the Tdap and/or flu vaccine significantly aggravated her predisposition to autoimmunity. Under such circumstances, the *Althen* test is expanded, and the petitioner has additional evidentiary burdens to satisfy. *See generally Loving*, 86 Fed. Cl. at 144. In *Loving*, the Court of Federal Claims combined the *Althen* test with the test from *Whitecotton v. Secretary of Health & Human Services*, 81 F.3d 1099, 1107 (Fed. Cir. 1996), which related to on-Table significant aggravation cases. The resultant "significant aggravation" test has six components, which are:

> (1) the person's condition prior to administration of the vaccine, (2) the person's current condition (or the condition following the vaccination if that is also pertinent), (3) whether the person's current condition constitutes a 'significant aggravation' of the person's condition prior to vaccination, (4) a medical theory causally connecting such a significantly worsened condition to the vaccination, (5) a logical sequence of cause and effect showing that the vaccination was the reason for the significant aggravation, and (6) a showing of a proximate temporal relationship between the vaccination and the significant aggravation.

Loving, 86 Fed. Cl. at 144; *see also W.C.*, 704 F.3d at 1357 (holding that "the *Loving* case provides the correct framework for evaluating off-table significant aggravation claims"). In effect, the last three prongs of the *Loving* test correspond to the three *Althen* prongs.

Subsumed within the *Loving* analysis is the requirement to evaluate the likely natural course of an injured party's pre-existing disease, in order to determine whether the vaccine made the petitioner worse than he would have been but for the vaccination. *Locane v. Sec'y of Health & Human Servs.,* 685 F.3d 1375, 1381–82 (Fed. Cir. 2012) (upholding special master's determination that petitioner had failed to carry her burden of proof in establishing that her pre-existing injury was worsened by the relevant vaccine); *Hennessey v. Sec'y of Health & Human Servs.*, No. 01-190V, 2009 WL 1709053, at *41–42 (Fed. Cl. Spec. Mstr. May 29, 2009), *mot. for review denied*, 91 Fed. Cl. 126 (2010). The critical point of examination is thus "whether the change for the worse in [petitioner's] clinical presentation was aggravation or a natural progression" of the underlying condition. *Hennessey*, 2009 WL 1709053, at *42.[14] The Federal Circuit has upheld the determinations of special masters that worsening was not demonstrated

[14] The legislative history of the Vaccine Act strongly supports interpreting "significant aggravation" as requiring a claimant to establish that a vaccine rendered a pre-existing condition qualitatively worse than it would have been otherwise—not simply that the affected individual experienced a post-vaccination symptom that contrasts with the individual's comparatively better pre-vaccination health. *See* H.R. Rep. No. 99-908, at 15 (1986) ("This [significant aggravation] provision does not include compensation for conditions which might legitimately be described as pre-existing (e.g., a child with monthly seizures who, after vaccination, has seizures every three and a half weeks), *but is meant to encompass serious deterioration* (e.g., a child with monthly seizures who, after vaccination, has seizures on a daily basis" (emphasis added)).

by a petitioner in connection with establishing her overall preponderant burden of proof for a non-Table causation-in-fact claim. *See, e.g., Snyder/Harris v. Sec'y of Health & Human Servs.,* 553 F. App'x 994, 999–1000 (Fed. Cir. 2014); *Locane*, 685 F.3d at 1381–82.[15]

Application of *Loving*'s "worsening" requirement has been the occasion for some disparate holdings by special masters as well as the Court. In some cases, evidence that an injured party was literally "worse" than she was immediately prior to the vaccination at issue has been viewed as sufficient to satisfy this prong. *See, e.g., Paluck v. Sec'y of Health & Human Servs.*, 113 Fed. Cl. 210, 232 (2013), *aff'd*, 786 F.3d 1373 (Fed. Cir. 2015). In other instances, however, the mere fact a vaccine might "trigger" a transient negative response in an individual with an underlying condition has not been deemed proof of worsening if that individual would be expected to experience a similar overall course regardless. *Faoro v. Sec'y of Health &Human Servs.*, No. 10-704V, 2016 WL 675491, at *27 (Fed. Cl. Spec. Mstr. Jan. 29, 2016), *mot. for review denied*, 128 Fed. Cl. 61 (Fed. Cl. Apr. 11, 2016) (finding that "the vaccinations would not have changed her clinical course and thus, the vaccinations did not significantly aggravate her pre-existing condition"). Federal Circuit precedent directly addressing this standard suggests the latter understanding is more accurate. *See, e.g., Locane*, 685 F. 3d at 1381 (upholding special master's denial of significant aggravation claim when evidence "showed that the course of [petitioner's] condition was not inconsistent with the disease generally").

C. *Law Governing Analysis of Fact Evidence*

The process for making determinations in Vaccine Program cases regarding factual issues begins with consideration of the medical records. Section 11(c)(2). The special master is required to consider "all [] relevant medical and scientific evidence contained in the record," including "any diagnosis, conclusion, medical judgment, or autopsy or coroner's report which is contained in the record regarding the nature, causation, and aggravation of the petitioner's illness, disability, injury, condition, or death," as well as the "results of any diagnostic or evaluative test which are contained in the record and the summaries and conclusions." Section 13(b)(1)(A). The special master is then required to weigh the evidence presented, including contemporaneous medical records and testimony. *See Burns v. Sec'y of Health & Human Servs*., 3 F.3d 415, 417 (Fed. Cir. 1993) (it is within the special master's discretion to determine whether to afford greater weight to contemporaneous medical records than to other evidence, such as oral testimony surrounding the events in question that was given at a later date, provided that such determination is evidenced by a rational determination).

[15] This is consistent with the fact (well recognized by controlling precedent) that evidence of "worsening" relevant to Respondent's alternative cause burden may reasonably by evaluated by a special master in determining the success of a petitioner's prima facie showing. *Snyder/Harris*, 553 F. App'x at 1000 (quoting *Stone v. Sec'y of Health & Human Servs.*, 676 F.3d 1373, 1380 (Fed. Cir. 2012) ("no evidence should be embargoed from the special master's consideration simply because it is also relevant to another inquiry under the statute")); *see also de Bazan*, 539 F.3d at 1353 ("[t]he government, like any defendant, is permitted to offer evidence to demonstrate the inadequacy of the petitioner's evidence on a requisite element of the petitioner's case-in-chief").

Medical records that are created contemporaneously with the events they describe are presumed to be accurate and "complete" (i.e., presenting all relevant information on a patient's health problems). *Cucuras*, 993 F.2d at 1528; *Doe/70 v. Sec'y of Health & Human Servs.*, 95 Fed. Cl. 598, 608 (2010) ("[g]iven the inconsistencies between petitioner's testimony and his contemporaneous medical records, the special master's decision to rely on petitioner's medical records was rational and consistent with applicable law"), *aff'd sub nom. Rickett v. Sec'y of Health & Human Servs*., 468 F. App'x 952 (Fed. Cir. 2011) (non-precedential opinion). This presumption is based on the linked propositions that (i) sick people visit medical professionals; (ii) sick people honestly report their health problems to those professionals; and (iii) medical professionals record what they are told or observe when examining their patients in as accurate a manner as possible, so that they are aware of enough relevant facts to make appropriate treatment decisions. *Sanchez v. Sec'y of Health & Human Servs.*, No. 11-685V, 2013 WL 1880825, at *2 (Fed. Cl. Spec. Mstr. Apr. 10, 2013); *Cucuras v. Sec'y of Health & Human Servs.*, 26 Cl. Ct. 537, 543 (1992), *aff'd*, 993 F.2d at 1525 (Fed. Cir. 1993) ("[i]t strains reason to conclude that petitioners would fail to accurately report the onset of their daughter's symptoms").

Accordingly, if the medical records are clear, consistent, and complete, then they should be afforded substantial weight. *Lowrie v. Sec'y of Health & Human Servs*., No. 03-1585V, 2005 WL 6117475, at *20 (Fed. Cl. Spec. Mstr. Dec. 12, 2005). Indeed, contemporaneous medical records are generally found to be deserving of greater evidentiary weight than oral testimony—especially where such testimony conflicts with the record evidence. *Cucuras*, 993 F.2d at 1528; *see also Murphy v. Sec'y of Health & Human Servs*., 23 Cl. Ct. 726, 733 (1991), *aff'd per curiam*, 968 F.2d 1226 (Fed. Cir. 1992), *cert. denied sub nom. Murphy v. Sullivan*, 506 U.S. 974 (1992) (citing *United States v. United States Gypsum Co.*, 333 U.S. 364, 396 (1947) ("[i]t has generally been held that oral testimony which is in conflict with contemporaneous documents is entitled to little evidentiary weight.")).

However, there are situations in which compelling oral testimony may be more persuasive than written records, such as where records are deemed to be incomplete or inaccurate. *Campbell v. Sec'y of Health & Human Servs*., 69 Fed. Cl. 775, 779 (2006) ("like any norm based upon common sense and experience, this rule should not be treated as an absolute and must yield where the factual predicates for its application are weak or lacking"); *Lowrie*, 2005 WL 6117475, at *19 ("[w]ritten records which are, themselves, inconsistent, should be accorded less deference than those which are internally consistent") (quoting *Murphy*, 23 Cl. Ct. at 733)). Ultimately, a determination regarding a witness's credibility is needed when determining the weight that such testimony should be afforded. *Andreu*, 569 F.3d at 1379; *Bradley v. Sec'y of Health & Human Servs*., 991 F.2d 1570, 1575 (Fed. Cir. 1993).

When witness testimony is offered to overcome the presumption of accuracy afforded to contemporaneous medical records, such testimony must be "consistent, clear, cogent, and compelling." *Sanchez*, 2013 WL 1880825, at *3 (citing *Blutstein v. Sec'y of Health & Human Servs*., No. 90-2808V, 1998 WL 408611, at *5 (Fed. Cl. Spec. Mstr. June 30, 1998)). In determining the accuracy and completeness of medical records, the Court of Federal Claims has listed four possible explanations for

inconsistencies between contemporaneously created medical records and later testimony: (1) a person's failure to recount to the medical professional everything that happened during the relevant time period; (2) the medical professional's failure to document everything reported to her or him; (3) a person's faulty recollection of the events when presenting testimony; or (4) a person's purposeful recounting of symptoms that did not exist. *Lalonde v. Sec'y of Health & Human Servs*., 110 Fed. Cl. 184, 203–04 (2013), *aff'd*, 746 F.3d 1334 (Fed. Cir. 2014). In making a determination regarding whether to afford greater weight to contemporaneous medical records or other evidence, such as testimony at hearing, there must be evidence that this decision was the result of a rational determination. *Burns*, 3 F.3d at 417.

D. *Analysis of Expert Testimony*

Establishing a sound and reliable medical theory often requires a petitioner to present expert testimony in support of his claim. *Lampe v. Sec'y of Health & Human Servs*., 219 F.3d 1357, 1361 (Fed. Cir. 2000). Vaccine Program expert testimony is usually evaluated according to the factors for analyzing scientific reliability set forth in *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579, 594–96 (1993). *See Cedillo v. Sec'y of Health & Human Servs.*, 617 F.3d 1328, 1339 (Fed. Cir. 2010) (citing *Terran v. Sec'y of Health & Human Servs.*, 195 F.3d 1302, 1316 (Fed. Cir. 1999)). "The *Daubert* factors for analyzing the reliability of testimony are: (1) whether a theory or technique can be (and has been) tested; (2) whether the theory or technique has been subjected to peer review and publication; (3) whether there is a known or potential rate of error and whether there are standards for controlling the error; and (4) whether the theory or technique enjoys general acceptance within a relevant scientific community." *Terran*, 195 F.3d at 1316 n.2 (citing *Daubert*, 509 U.S. at 592–95).

The *Daubert* factors play a slightly different role in Vaccine Program cases than they do when applied in other federal judicial fora (such as the district courts). *Daubert* factors are usually employed by judges (in the performance of their evidentiary gatekeeper roles) to exclude evidence that is unreliable and/or could confuse a jury. In Vaccine Program cases, by contrast, these factors are used in the *weighing* of the reliability of scientific evidence proffered. *Davis v. Sec'y of Health & Human Servs*., 94 Fed. Cl. 53, 66–67 (2010) ("uniquely in this Circuit, the *Daubert* factors have been employed also as an acceptable evidentiary-gauging tool with respect to persuasiveness of expert testimony already admitted"). The flexible use of the *Daubert* factors to evaluate the persuasiveness and reliability of expert testimony has routinely been upheld. *See, e.g.*, *Snyder*, 88 Fed. Cl. at 742–45. In this matter (as in numerous other Vaccine Program cases), *Daubert* has not been employed at the threshold, to determine what evidence should be admitted, but instead to determine whether expert testimony offered is reliable and/or persuasive.

Respondent frequently offers one or more experts of his own in order to rebut a petitioner's case. Where both sides offer expert testimony, a special master's decision may be "based on the credibility of the experts and the relative persuasiveness of their competing theories." *Broekelschen*, 618 F.3d at 1347 (citing *Lampe*, 219 F.3d at 1362). However, nothing requires the acceptance of an expert's conclusion

"connected to existing data only by the *ipse dixit* of the expert," especially if "there is simply too great an analytical gap between the data and the opinion proffered." *Snyder*, 88 Fed. Cl. at 743 (quoting *Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 146 (1997)); *see also Isaac v. Sec'y of Health & Human Servs*., No. 08-601V, 2012 WL 3609993, at *17 (Fed. Cl. Spec. Mstr. July 30, 2012), *mot. for review denied*, 108 Fed. Cl. 743 (2013), *aff'd*, 540 F. App'x 999 (Fed. Cir. 2013) (citing *Cedillo*, 617 F.3d at 1339). Weighing the relative persuasiveness of competing expert testimony, based on a particular expert's credibility, is part of the overall reliability analysis to which special masters must subject expert testimony in Vaccine Program cases. *Moberly*, 592 F.3d at 1325–26 ("[a]ssessments as to the reliability of expert testimony often turn on credibility determinations"); *see also Porter v. Sec'y of Health & Human Servs*., 663 F.3d 1242, 1250 (Fed. Cir. 2011) ("this court has unambiguously explained that special masters are expected to consider the credibility of expert witnesses in evaluating petitions for compensation under the Vaccine Act").

Expert opinions based on unsupported facts may be given relatively little weight. *See Dobrydnev v. Sec'y of Health & Human Servs.*, 556 F. App'x 976, 992–93 (Fed. Cir. 2014) ("[a] doctor's conclusion is only as good as the facts upon which it is based") (citing *Brooke Group Ltd. v. Brown & Williamson Tobacco Corp.*, 509 U.S. 209, 242 (1993) ("[w]hen an expert assumes facts that are not supported by a preponderance of the evidence, a finder of fact may properly reject the expert's opinion")). Expert opinions that fail to address or are at odds with contemporaneous medical records may therefore be less persuasive than those which correspond to such records. *See Gerami v. Sec'y of Health & Human Servs.*, No. 12-442V, 2013 WL 5998109, at *4 (Fed. Cl. Spec. Mstr. Oct. 11, 2013), *aff'd*, 127 Fed. Cl. 299 (2014).

E. *Consideration of Medical Literature*

Both parties filed medical and scientific literature in this case, but not every filed item factors into the outcome of this decision. While I have reviewed all of the medical literature submitted in this case, I discuss only those articles that are most relevant to my determination and/or are central to Petitioner's case—just as I have not exhaustively discussed every individual medical record filed. *Moriarty v. Sec'y of Health & Human Servs.*, 844 F.3d 1322, 1328 (Fed. Cir. 2016) ("[w]e generally presume that a special master considered the relevant record evidence even though he does not explicitly reference such evidence in his decision") (citation omitted); *see also Paterek v. Sec'y of Health & Human Servs.,* 527 F. App'x 875, 884 (Fed. Cir. 2013) ("[f]inding certain information not relevant does not lead to—and likely undermines—the conclusion that it was not considered").

F. *Resolution of Case Via Ruling on Record*

I have opted to resolve this matter on the papers, rather than by holding a hearing. The Vaccine Act and Rules not only contemplate but encourage special masters to decide petitions on the papers where (in the exercise of their discretion) they conclude that doing so will properly and fairly resolve the case. Section 12(d)(2)(D); Vaccine Rule 8(d). The decision to rule on the record in lieu of hearing has been affirmed on appeal. *See Hooker v. Sec'y of Health & Human Servs.*, No. 02-472V, 2016 WL 3456435, at

*21 n.19 (Fed. Cl. Spec. Mstr. May 19, 2016) (citing numerous cases where special masters decided on the papers in lieu of hearing and that decision was upheld). I am simply not required to hold a hearing in every matter, no matter the preferences of the parties. *Hovey v. Sec'y of Health & Human Servs*., 38 Fed. Cl. 397, 402–03 (1997) (special master acted within his discretion in denying evidentiary hearing); *Burns*, 3 F.3d at 417; *Murphy v. Sec'y of Health & Human Servs.*, No. 90-882V, 1991 WL 71500, at *2 (Cl. Ct. Spec. Mstr. Apr. 19, 1991).

ANALYSIS

I. Petitioner's Illness is Best Characterized as RMD

A fundamental matter to be resolved before application of the *Althen* prongs is determining the actual nature of Petitioner's injury. Petitioner, supported by the diagnostic views of multiple treating doctors and Dr. Rinker, maintains that she suffered from RMD. Mot. at 10–14. Respondent, by contrast, urges me to adopt Dr. Chaudhry's view that Ms. Sheets only suffers from a myopathy or myositis attributable to her pre-existing connective tissue disease, rather than RMD. Opp. at 10–11.

As explained in medical literature filed by both parties, RMD is a rare myopathy featuring muscle stiffness, muscle hypertrophy, and involuntary muscle contractions that create a rippling effect. T. Torbergsen, *Rippling Muscle Disease: A Review*, 11 Muscle & Nerve Supp. S103, S103 (2002), filed as Ex. D, Apr. 12, 2018 (ECF No. 24-4) ("Torbergsen"); M. Bettini, et al., *Immune-Mediated Rippling Muscle Disease and Myasthenia Gravis*, 299 J. Neuroimmunology 59, 59 (2016), filed as Ex. 40, Oct. 30, 2017 (ECF No. 17-4) ("Bettini"). It can be hereditary, resulting from variations in the caveolin-3-encoding gene, or it can be acquired immunogenically. Bettini at 59. The parties' respective experts concur that Petitioner's alleged RMD was not hereditary, as demonstrated by genetic testing. *See* First Rinker Rep. at 4; Chaudhry Rep. at 10–11; Ex. 22 at 435. When acquired, RMD is generally (though not always) associated with myasthenia gravis. Bettini at 59–60. RMD is characterized as a relatively mild disorder, and it is non-progressive. Torbergsen at S105.

Here, and despite reasoned points raised by Respondent's expert about deficiencies in the diagnosis, the medical record (when viewed in its entirety) better supports Petitioner's proposed diagnosis. Although Petitioner's treating physicians regularly (and reasonably, given Petitioner's history) included myopathy related to pre-existing connective tissue disease among their earlier differential diagnoses, over time they eventually coalesced around a diagnosis of RMD. *See, e.g.*, Ex. 6 at 1–4 (Dr. Edwards characterizing Petitioner's symptoms in April 2014 as "possibly related to . . . mixed connective tissue disease"); Ex. 3 at 8–9 (August 2014 biopsy of left quadriceps findings were "suggestive of myopathy"), 62–65 (Dr. Wicklund's July 2015 differential diagnosis listing "rippling muscle disease, lupus, perhaps neuromuscular junction disease, and perhaps muscular disease on an autoimmune basis"); Ex. 23 at 38–44 (EMG performed July 2015 consistent with "mild, chronic myopathy with rippling muscles"). This,

and the fact that Petitioner's symptoms—most notably, her well-documented rippling muscles—are generally consistent with RMD as it is described in the filed medical literature, support Petitioner's argument as to the proper diagnosis.

However, I also find that, based upon the record, it is most likely that Petitioner's RMD was associated with her pre-existing connective tissue disease. Certainly her treaters proposed as such. *See, e.g.*, Ex. 29 at 1 (Dr. Albano-Aluquin describing petitioner's symptoms as a "flare[]" of her mixed autoimmune disease). Dr. Rinker also acknowledged that "autoimmunity, once established, is a chronic condition which may manifest with recurrent or even new symptoms over time," and ultimately allowed (in his final expert report) that "[Petitioner's] RMD is best viewed as a continuation of her previously diagnosed autoimmune condition, rather than a completely *de novo* condition." Third Rinker Rep. at 2. Petitioner did not otherwise successfully distinguish her pre-vaccination symptoms, other than to argue that they merely reflected a susceptibility to autoimmunity or were milder in severity. In fact, the record suggests that this purported susceptibility manifested in a form that was on a continuum with the symptoms that later led treaters to identify RMD as a proper diagnosis.

II. Petitioner Has Not Satisfied the *Althen* Prongs

A. *Prong One*

Although the evidence preponderates in favor of the RMD diagnosis, I cannot also find that Petitioner has demonstrated that the flu and/or tetanus vaccines "can cause" RMD, because the components of the theory offered by Dr. Rinker are too piecemeal and nonspecific to constitute a reliable scientific or medical causation theory. This is the primary deficiency in Petitioner's overall showing.

In his expert reports, Dr. Rinker broadly lists a variety of mechanisms by which vaccines can purportedly cause different autoimmune conditions, but he fails to persuasively link (with reliable scientific evidence, or on the basis of his own expertise) these theories to either the vaccines in question or Petitioner's own specific condition. Thus, he describes the general concept of molecular mimicry as a mediator of *other* autoimmune diseases (for example, idiopathic thrombocytopenic purpura,[16] or GBS), but does not establish that the acquired form of RMD is *itself* also mediated via an autoimmune cross-reaction. *See* First Rinker Rep. at 6. As I have previously stated, when attempting to establish a causal mechanism, "[p]etitioners cannot simply invoke the concept of molecular mimicry and call it a day." *Johnson v. Sec'y of Health & Human Servs.*, No. 14-254V, 2018 WL 2051760, at *26 (Fed. Cl. Spec. Mstr. Mar. 23, 2018). Dr. Rinker has also offered nothing suggesting that any relevant vaccine components could act as an antigenic stimulant sufficient to cause the production of autoantibodies associated with the version of RMD Petitioner is believed to have had. Without more, Petitioner cannot succeed on the theory

[16] Idiopathic thrombocytopenic purpura, also known as immune thrombocytopenic purpura, is a condition characterized by a decrease in platelet count. *Johnson v. Sec'y of Health & Human Servs.*, No. 14-113V, 2017 WL 772534, at *1 n.3 (Fed. Cl. Spec. Mstr. Jan. 6, 2017); *Dorland's* at 1557.

of molecular mimicry as explanatory in this case simply because it was applicable to other kinds of autoimmune diseases.

The other components of Dr. Rinker's theory are to an even greater extent too generalized and vague to satisfy *Althen* prong one. Thus, Dr. Rinker discusses the role of vaccine adjuvants, explaining correctly that they increase a vaccine's immune response. First Rinker Rep. at 6. However, while he maintains that adjuvants can cause "a more widespread activation of the immune response directed at antigens other than those included in the vaccine itself," the only medical literature he relies on for this point is Murphy-Ullrich, a 1984 study which Dr. Rinker concedes showed *no* pathogenic effects. *Id.* (citing Murphy-Ullrich). I have in other cases noted that petitioners cannot invoke the expected role an adjuvant plays in aiding immunogenicity of a vaccine to also establish the same vaccine's pathogenic capacity, without some reliable scientific or medical evidence that demonstrates how this would occur. *See, e.g.*, *Johnson*, 2018 WL 2051760, at *8 n.11. In addition, the flu vaccine administered in the United States does not even contain an adjuvant, and Dr. Rinker's reports make no showing with respect to the adjuvants contained in the Tdap vaccine.

Dr. Rinker's reports also discuss HLA and T cells, but he has not coherently or persuasively explained what role these elements could have played in Ms. Sheets's case. In particular, he does not identify any pertinent information regarding her specific HLA profile, nor does he explain how it would increase the likelihood of an autoimmune reaction after vaccination.[17] His discussion of HLA at best shows that some persons might have a propensity for autoimmune disease, but does not lead to the conclusion that this propensity means a person who receives a vaccine will likely have a specific negative autoimmune reaction. And fundamentally, Dr. Rinker does not possess the expertise necessary to opine on the conceptual pathogenic effects of vaccination. He has merely offered some ideas about how vaccines might generally do harm. He has not explained how the flu or Tdap vaccine in this case could cause RMD or a similar condition. This showing is insufficient to amount to a reliable scientific theory in satisfaction of the first *Althen* prong.[18]

Finally, while Petitioner encourages me to consider the opinions of her treating physicians as evidence supporting Dr. Rinker's causation theory, these views do little to strengthen Petitioner's showing on the first *Althen* prong. While treater opinions regarding possible vaccine causation are entitled to some weight, they do not bind me *per se*. Section 13(b)(1); *Snyder*, 88 Fed. Cl. at 746 n.67. Here, the opinions

[17] By contrast, petitioners have in other cases succeeded in demonstrating that a particular HLA is associated with a specific disease. *McCollum v. Sec'y of Health & Human Servs.*, No. 14-790V, 2017 W: 5386613, at *4 .n16 (Fed. Cl. Spec. Mstr. Sept. 15, 2017), *mot. for review denied*, 135 Fed. Cl. 735 (2017), *aff'd*, 2019 WL 928499 (Fed. Cir. Feb. 25, 2019). In so doing, they invoked persuasive and reliable medical literature specific to the illness at issue. *See id.* This has not been done in this case with respect to RMD.

[18] Petitioner's assertion that mere plausibility alone is sufficient to satisfy *Althen* prong one mischaracterizes her ultimate burden satisfying each *Althen* prong with preponderant evidence. *See Broekelschen*, 618 F.3d at 1350. Given its facial weaknesses and speculative quality, however, I would not find that Petitioner's proffered theory meets even a lower standard of mere plausibility.

offered by Drs. Albano-Aluquin, Simmons, and Wicklund were not contemporaneous with Petitioner's onset, as none of these medical professionals were treating her anytime before the fall of 2014—months after both vaccination and alleged onset. Moreover, Drs. Albano-Aluquin and Wicklund offered only equivocal opinions. *See* Ex. 31 at 37–41, 241–42, 273–74. And none of the treater opinions offered in this case provided any more specificity or clarity with regards to a mechanism of causation than did the reports provided by Dr. Rinker—that is, none explained how the flu and/or Tdap vaccine could have caused RMD. For these reasons, I find the treater statements supporting the possibility of vaccine causation to be of little value in the resolution of this case.

B. *Prong Two*

Although Petitioner argues that she developed RMD almost immediately post-vaccination, it cannot be disputed that she had a pre-existing connective tissue disease as of 2010, three years prior to receipt of the flu and Tdap vaccines. Ex. 2 at 4. Dr. Rinker proposes that Petitioner was "in remission" as of December 2013 (*see* First Rinker Rep. at 1, 5, 8), but the medical records suggest that she continued to exhibit related symptoms around the time of vaccination (although they may have been less severe than in the past). *See, e.g.*, Ex. 36 at 6–11 (reports of fatigue and abdominal pain in December 2013).

Even though Respondent did not carry the day on the diagnosis issue, on the point of connecting Petitioner's overall symptomology pre and post-vaccination, Respondent had the better argument. As Dr. Chaudhry explained in his report, Ms. Sheets's myopathy symptoms were consistent with an ongoing autoimmune disease that flared in the spring and summer of 2014 (more than three months post-vaccination). *See* Chaudhry Rep. at 11. Dr. Rinker, by contrast, did not successfully distinguish Petitioner's post-vaccination symptoms from her earlier autoimmune condition. Indeed, both Drs. Rinker and Albano-Aluquin appear to *agree* that Ms. Sheets's RMD is best understood to be a "continuation of her previously diagnosed autoimmune condition" or a "flare[]." *See* Third Rinker Rep. at 2; Ex. 29 at 1. If so, the flu and/or Tdap vaccine could not have been the cause-in-fact of her illness.

Petitioner was not otherwise able to establish with preponderant evidence that the Tdap or flu vaccine triggered any of her post-vaccination symptoms. As a threshold matter, her medical records do not reveal that she actually experienced any vaccine reaction, and there is a large gap in the records before Ms. Sheets sought care for new muscle-related symptoms in the spring of 2014, allowing for the inference that no noteworthy symptoms necessitating treatment in the preceding winter had occurred. Petitioner attempts to fill in such evidentiary "gaps" in her medical history with witness testimony purporting to establish an onset closer in time to vaccination, and such evidence[19] is worthy of some weight—especially since it was not expressly rebutted, and is also roughly consistent with statements she made to treaters in April 2014 about when she first experienced her symptoms. *See, e.g.*, Ex. 6 at 1 (note from April 23, 2014

[19] I give far less weight to Dr. Rinker's statements about onset timing, as his recount of Petitioner's onset was based on Ms. Sheets's own after-the-fact statements, rather than contemporaneous observation.

visit describing symptom onset on December 20, 2013; noting that symptoms began after receiving flu vaccine).

But even if I credit as accurate such allegations, evidence of an earlier onset does not rebut my determination that Petitioner's overall course began *prior* to vaccination. Moreover, Ms. Sheets's medical record suggests that there was an alternative explanation for her new symptoms: her MRSA infection. *See* Chaudhry Rep. at 11; Ex. 36 at 9–10 (noting probable recurrent MRSA infection at December 4, 2013 visit). Respondent established that this infection is a reasonable alternative explanation for any new symptoms experienced by Petitioner, given that bacterial infections are known to trigger polymyositis and dermatomyositis. *See* Chaudhry Rep. at 11 (citing Ex. C; Ex. F). Dr. Rinker never rebutted the relevance of the MRSA infection, stating instead (contrary to the record) that "there is no mention in the medical record of infectious illness" that could be the "immunological stimulus" for Petitioner's myopathy symptoms. Third Rinker Rep. at 2. This omission greatly undercuts the strength of Petitioner's *Althen* prong two showing, especially given that her expert's opinion was premised on the "the absence of alternative causes." *See* Third Rinker Rep. at 2. I cannot give substantial weight to this aspect of Dr. Rinker's opinion about vaccine causation when it fails to address a significant aspect of Petitioner's medical record. *See Dobrydnev*, 556 F. App'x at 992–93 (citing *Brooke Group Ltd.*, 509 U.S. at 242 (finding expert opinions based on unsupported factual allegations to be worthy of little to no weight)).[20]

The weakness in Petitioner's showing on the question of actual causation is best seen in the evolution of her own expert's view over the course of his three reports. Dr. Rinker began by suggesting that the vaccines could have caused her RMD (*see generally* First Rinker Rep.), but ultimately opined that the vaccines in fact significantly aggravated her ongoing "systemic autoimmunity." Third Rinker Rep. at 3. In effect, it appears he realized that Ms. Sheets's pre-existing symptoms simply could not be divorced from her later RMD diagnosis. It is well understood in the Program that a claimant cannot recover a damages award if her symptoms predate vaccination. *Shalala v. Whitecotton*, 514 U.S. 268, 274–75 (1995) (Vaccine Act claimant who demonstrates she experienced symptoms of injury after receipt of vaccination does not succeed in her claim if the evidence fails to indicate that she had no symptoms of injury before her vaccination); *Locane v. Sec'y of Health & Human Servs.*, 99 Fed. Cl. 715 (2011), *aff'd*, 685 F.3d 1375 (Fed. Cir. 2012) (petitioner's Crohn's disease began prior to her vaccinations and therefore vaccine causation could not be established). Petitioner has not demonstrated a logical sequence of cause and effect sufficient to satisfy the second *Althen* prong.

[20] Based on the available medical records, Petitioner's contention that no treater deemed her MRSA infection a likely trigger for her RMD appears to be true. *See, e.g.*, Ex. 33 at 3. However, this fact does little to bolster Petitioner's showing on the second *Althen* prong. Petitioner did not report her RMD symptoms to treaters until spring of 2014, at which time she appears to have self-reported the close temporal relationship between her symptom onset and her December 23, 2013 vaccinations. *See, e.g., id.* It is thus unclear whether her treaters were even aware of her December 2013 MRSA infection. Given that treaters would likely prioritize accurate diagnosis and treatment over a determination of the etiology of Ms. Sheets's rare condition, this dearth of independent treater discussion regarding the cause of her RMD is unsurprising.

C. *Prong Three*

Dr. Rinker concedes that an onset for Ms. Sheets's symptoms more than a few weeks after vaccination would greatly decrease the likelihood of vaccine causation under his proffered theory. *See* Second Rinker Rep. at 2. Determining onset in this case requires comparison of the medical record to witness statements prepared after the fact. The medical records created close in time to December 2013 unquestionably do not corroborate allegations of an immediate post-vaccination onset. In her first five doctor's visits following vaccination, Ms. Sheets made no mention of her symptoms to treaters. *See* Ex. 3 at 14–15 (January 3, 2014 surgery for pelvic mass removal); Ex. 36 at 4–5 (January 13th post-operative visit); Ex. 4 at 1 (denying leg cramps at January 17th cardiologist visit), 4 (denying leg cramps at January 23rd cardiologist visit); Ex. 5 at 1–4 (no mention of rippling muscles at March 5th rheumatologist visit). Given her pre-vaccination history, it is not unreasonable to expect that Ms. Sheets might have informed some of these treaters of new symptoms different than what she had experienced prior to vaccination.

Ms. Sheets relies heavily on witness statements and on later-in-time medical records containing self-reported onset history to bulwark her position regarding onset. These statements—which Respondent has not effectively rebutted—do provide evidentiary support for Petitioner's claimed onset, as witness statements can fill in "blanks" in a medical record that simply omits details. *See Campbell*, 69 Fed. Cl. at 779. At the same time, however, contemporaneous medical records are presumed not only accurate, but also complete, and later-in-time statements (whether made to treaters or prepared for purposes of litigation) do not suffice to contradict such records. *Cucuras*, 993 F.2d at 1528; *Murphy*, 23 Cl. Ct. at 733.

Ultimately, determining onset in this case presents a close question. Although Ms. Sheets's allegations, and the statements of her contemporaneous witnesses, are not corroborated by independent medical records, I find she has offered just enough proof to conclude that onset likely occurred closer in time to vaccination than Respondent allows. This success, however, is not sufficient basis upon which to find in Petitioner's favor overall—both because her theory of causation itself is significantly deficient, and because (as noted above) the record suggests it more likely than not that Petitioner's illness *predated* vaccination. At most, this record allows for the conclusion that Petitioner's pre-existing connective tissue disease symptoms flared up in the weeks after vaccination, but were not deemed by her significant enough to seek treatment until April. Such a fact pattern lends support to the conclusion that her later-diagnosed RMD was associated with, rather than distinguishable from, her earlier, pre-vaccination connective tissue disease symptoms.

III. The Tdap and Flu Vaccines Did Not Significantly Aggravate Petitioner's Pre-existing Condition

Ms. Sheets's medical record does suggest a recurring condition, although she defines it in inconsistent and highly generalized terms, varyingly describing it as a "neurologic illness," "systemic autoimmunity," and "predisposition to autoimmunity." Mot. at 22, 24, 25. Even though she cannot on the

existing record establish that the vaccines she received caused her condition later manifesting as RMD, she could prevail if she successfully demonstrated that the vaccines *aggravated* it. However, I find that she has failed to do so.

Setting aside Petitioner's failure to satisfy the first two *Althen* prongs (both of which are subsumed under *Loving*), I find that she has not shown with credible and reliable evidence that either or both of the vaccines at issue caused her overall course to be more severe than it would have been expected to be otherwise. Indeed, as noted above, the evidence is equivocal in support of the conclusion that she had *any* immediate post-vaccination symptoms at all—and to the extent she did, her symptoms appear to have been relatively mild for several months before flaring up in the spring and summer of 2014, causing her to delay mention of the problem to treaters (and to fail to mention it to those treaters she did see in the months post-vaccination). This kind of history is not consistent with the theory that vaccination resulted in a significant change for the worse. At best, Petitioner's post-vaccination condition featured some symptoms that she had not previously experienced (such as rippling muscles), but this is inadequate support for the proposition that her overall course would have been milder but for her December 23, 2013 vaccinations. Dr. Rinker otherwise did not establish *how* vaccination would worsen Petitioner's condition, nor did he persuasively describe the process by which the vaccines purportedly "did cause" the alleged post-vaccination significant aggravation.

IV. This Matter was Properly Resolved Without a Hearing

In ruling on the record, I am declining to hold a hearing, as Petitioner has requested. Mot. at 2. The choice of how best to resolve this case is a matter that lies generally within my discretion, but I will briefly explain my reasoning here.

A hearing provides a petitioner with the opportunity to put on live testimony, which aids the special master most in cases where witness credibility is at issue or where there is a need to pose questions to a witness in order to obtain information not contained in, or not self-evident from, the existing filings. *See, e.g.*, *Hooker*, 2016 WL 3456435, at *21 (discussing a special master's discretion in holding a hearing and the factors that weighed against holding a hearing in the matter); *Murphy*, 1991 WL 71500, at *2 (no justification for a hearing where the claim is fully developed in the written records and the special master does not need to observe the fact witnesses for the purpose of assessing credibility). It may also permit a claimant to expand upon or illuminate points already set forth in written filings, or respond to unanticipated questions raised in the matter—but again, only where necessary to reach a decision.

Prior decisions have recognized that a special master's discretion in deciding whether to conduct an evidentiary hearing "is tempered by Vaccine Rule 3(b)," or the duty to "afford[] each party a full and fair opportunity to present its case." *Hovey*, 38 Fed. Cl. at 400–01 (citing Rule 3(b)). But that rule also includes the obligation of creation of a record "sufficient to allow review of the special master's decision." *Id*. Thus, the fact that a claim is legitimately disputed, such that the special master must exercise his

intellectual faculties in order to decide a matter, is not itself grounds for a trial (for if it were, trials would be required in every disputed case). Special masters are expressly empowered to resolve fact disputes *without* a hearing.

In this case, live witness testimony was not required in order for me to reach a reasoned decision. The flaws in Petitioner's theory of causation—the most glaring weakness in her overall showing—were self-evident from my review of the medical records and the three reports submitted by Dr. Rinker (who ultimately did not possess the expertise necessary to establish a persuasive causation theory). Such deficiencies did not require oral testimony to be understood for purposes of deciding the case. My experience in resolving vaccine injury claims informs my reading of the proffered theory of causation, and its impermissible vagueness and unreliability was apparent on its face. This case turns largely on whether I accepted Petitioner's causation theory, and hearing live testimony from the experts would not have increased the likelihood of such acceptance.

I similarly had no need to hear from Petitioner (or her several fact witnesses) directly. While there is some ambiguity with regard to when she began to experience RMD symptoms, I have ultimately determined that preponderant evidence (as established by declarations and witness statements) supported her contention that her RMD symptoms began not long after vaccination. However, the outcome of this case turned on the persuasiveness of Petitioner's causation theory, and the degree to which she established that her pre-existing condition was unrelated to and/or worsened by her vaccinations. These matters could be decided without any fact testimony. Hearing testimony that Ms. Sheets experienced symptoms earlier than her medical records indicated would, at most, serve to bulwark the temporal nexus between vaccination and the onset of her RMD—not strengthen the overall causation theory.

At bottom, the most significant issue in deciding whether to hold a hearing is determining if the refusal to do so will deprive the claimant of the fair opportunity to prosecute her case. Petitioner here has received such an opportunity. Her chances of winning would not have increased if I had opted to hold a hearing.

CONCLUSION

The Vaccine Act permits me to award compensation to a petitioner alleging a "non-Table Injury" only if she can show by medical records or competent medical opinion that the injury was more likely than not vaccine-caused. Here, Petitioner's claim depends upon my finding that she experienced post-vaccination onset of RMD or significant aggravation of an underlying autoimmune condition, but the weight of the evidence does not support either conclusion. Thus, there is insufficient evidence to support an award of compensation, leaving me no choice but to hereby **DENY** this claim.

In the absence of a timely-filed motion for review (see Appendix B to the Rules of Court), the Clerk shall enter judgment in accord with this decision.[21]

IT IS SO ORDERED.

/s/ Brian H. Corcoran
Brian H. Corcoran
Special Master

[21] Pursuant to Vaccine Rule 11(a), the parties may expedite entry of judgment by filing a joint notice renouncing their right to seek review.